SUMMARY MINUTES

OF THE

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE MEETING

Open Session

April 19, 2004
Gaithersburg Holiday Inn
Gaithersburg, MD

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE MEETING
APRIL 19, 2004

COMMITTEE PARTICIPANTS

Maryanne Harvey, MS	Chair
James F. Camburn, BS	
E. Scott Ferguson, MD	
Miles G. Harrison, Jr., MD	
Jessica W. Henderson, PhD	Consumer Representative
Carolyn B. Hendricks, MD	
Andrew Karellas, PhD	
Melissa C. Martin, MS	
Carol J. Mount, RT, (R), (M)	
Linda S. Pura, RN, MPA	Consumer Representative
Catalina R. Ramos-Hernandez, MD	Consumer Representative
Amy R. Rigsby, RT (M)	
Julie E. Timins, MD	

FDA PARTICIPANTS

Charles Finder, MD	Committee Executive Secretary Associate Director Division of Mammography Quality and Radiation Programs
Helen Barr, MD	Acting Director Division of Mammography Quality and Radiation Programs
Michael Divine, MS	Inspection and Compliance Branch Division of Mammography Quality and Radiation Programs
Robert Phillips, PhD	Radiological Devices Branch Division of Reproductive, Abdominal, and Radiological Devices

CALL TO ORDER

Committee Chair Maryanne Harvey, MS, called the meeting to order at 9:00 a.m. She noted for the record that the committee members present constituted a quorum and asked the panel to introduce themselves. Charles Finder, MD, read the conflict of interest statement. Full waivers had been granted to the following participants because of their financial involvement with organizations could be affected by the committee's deliberations: James F. Camburn, BS, E. Scott Ferguson, MD, Maryanne Harvey, MS, Jessica W. Henderson, PhD, Andrew Karellas, PhD, Carol J. Mount, RT (R)(M), and Julie E. Timins, MD. Waivers are currently on file for Miles G. Harrison, Jr., MD, Carolyn B. Hendricks, MD, Melissa C. Martin, MS, Linda S. Pura, RN, MPA, Catalina R. Ramos-Hernandez, MD, and Amy R. Rigsby, RT.

APPROVAL OF ALTERNATIVE STANDARDS

Dr. Finder reviewed the circumstances under which the Agency can approve an alternative standard. Since the committee's last meeting, the division has approved five alternative standards; two deal with the amount of time a facility has to correct problems when components of certain Full Field Digital Mammography (FFDM) systems fail quality control tests, and three deal with assessment categories. Information on the alternatives is available on the CDRH Mammography Web site.

OPEN PUBLIC HEARING

Ms. Harvey read the FDA's statement on disclosure with respect to the open public speaker process.

Murray A. Reicher, MD, Radiology Medical Group, Inc., DR Systems, Inc, San Diego, CA, presented his ideas on the best way to optimize mammography accuracy, safety, and cost. The primary factors involved include expertise of readers; adjunct technology and methods, such as CAD, double reading, and technologist's preview of clinical images; image acquisition technology quality, cost, and efficiency; required technologies for display, archive, and transport of digital or film screen mammography; and the cost of mandated regulatory activities. Factors that control accuracy, safety, and cost are not always aligned. For example, digital technology may increase quality, but it also increases costs. Optimization of mammography requires an understanding of the balance between quality, safety, and cost and the determinants of each factor.

Incremental improvements in technology have a far smaller effect on safety, quality, and cost than does the expertise of the reader. The published evidence on FFDM compared with film-screen technology shows marginal, if any, statistically proven differences in quality. CAD and double reading result in a 5 to 20 percent increase in cancer detection rate, but with increased cost and false positives. Expert readers lead to a 150 to 200 percent increase in cancer detection rates, with lower costs and fewer false positives. However, expert reading is impractical and not financially viable. To promote expert reading, mammograms must be cost-effectively transportable, and production costs must decrease to provide a financial incentive for providers. Digitizing film-screen mammograms can increase their transportability, but doing so involves data compression issues. FDA should consider allowing users and their physicists to document that the data compression technology they use does not alter image quality. Improving mammography safety, accuracy, and cost can be best achieved by enabling and promoting

technologies that increase the probability of reading by experts. A clear and logical policy is needed for film-screen versus soft copy mammograms.

Jerry A. Thomas, MSc, Chief of Radiological Physics, Department of Radiology/ Nuclear Medicine, Uniformed Services University of the Health Sciences (USUHS), discussed issues related to data compression, including storage limitations, transport of image sets, and "lossy" compression. Lossy data can be categorized as analytically, visually, or diagnostically lossless. No one has conducted a critical analysis of these three types of compression. Work has been done on the impact of compression on the ability to visualize content. Initial results from Thomas's lab show that lossy compression of an 8:1 or 10:1 ratio does not affect the diagnostic quality of mammograms. Compression method and analytical loss are the most important factors in image quality. One can have lossy data, but it can be displayed so that the image appears to be lossless.

OPEN COMMITTEE DISCUSSION

Helen Barr, MD, Acting Director, Division of Mammography Quality and Radiation Programs (DMQRP), CDRH, summarized the status of MQSA reauthorization. While MQSA expired on September 30, 2002, its inspection and certification authority did not sunset. Therefore the program continues to inspect and certify mammography facilities. The delay in reauthorization primarily involves concerns about issues related to physician interpretive skills. Dr. Barr described this and other aspects of the proposed legislation, which is currently in the House.

Dr. Barr then updated the committee on the inspection demonstration program (IDP). The IDP began in mid-2002 to assess whether violation-free facilities could maintain their status

without an annual inspection. Early incomplete results show that of the facilities that skipped an inspection, only 58 percent had no violations in the subsequent inspection, compared with 76 percent of the control group. The results suggest that annual scrutiny helps facilities maintain a higher level of nonviolation. Although the results are preliminary and incomplete, the FDA has elected not to extend the IDP, and all facilities will have annual inspections.

Dr. Barr then discussed the FDA's program to extend certification to include full-field digital mammography (FFDM). FDA's certification extension program was implemented in June 2000; it extended existing film-screen certification to include use of FFDM units if a facility met certain requirements. FDA used that program until it approved accrediting bodies to take over that function. The ACR and the State of Iowa are each responsible for accrediting different types of FFDM units. Because no accrediting body is approved to accredit the most recently approved devices, the agency continues to extend certificates to allow facilities to use those new units.

Michael P. Divine, MS, Inspection and Compliance Branch, DMQRP, described the inspection process, the different levels of violations, and the Agency's response to each level. The process for issuing warning letters changed as of October 1, 2003. Now, facilities that have Level 1 or repeat Level 2 violations are asked for a response within 15 days instead of being sent a warning letter. Previously, many facilities with those violations received a warning letter. This approach prevents having to send a warning letter for problems that may be corrected by the time the letter arrives. If the response to Level 1 or 2 violations is unsatisfactory or missing, FDA initiates further contact with the facility. If further contact does not result in a satisfactory resolution, FDA may conduct a follow-up inspection. If the follow-up inspection shows continuing problems, FDA then issues a warning letter. If the facility has received a previous warning letter, regulatory action comes into play. A follow-up compliance inspection takes place

2 to 3 months after the warning letter is issued; if that inspection shows continuing problems, regulatory action is possible. The goal of the new process is to build a compliance history to justify taking regulatory action for facilities that fail to correct problems.

The number of facilities with no problems has been increasing; Level 1 and 3 violations are flat, and Level 2 violations have diminished. The new strategy should result in quicker facility response to serious observations. More effective correction will take place, motivated by the prospect of follow-up inspection. The changes will result in more meaningful warning letters being sent and regulatory action being taken against the worst offenders.

MECHANISMS TO REDUCE THE REGULATORY AND INSPECTION BURDENS ON FACILITIES

Committee Chair Harvey read the directions for discussion and noted that the committee was being asked to discuss ways to reduce the regulatory and inspection burdens on facilities.

Personnel Issues: Amy Rigsby—discussion moderator

Ms. Rigsby noted that the topic includes initial qualifications, licenses, continuing education, and the number of mammograms performed and read annually. Ms. Rigsby noted that facilities should have all the necessary documentation ready for the inspector at the time of inspection. She also believed that annual inspections were appropriate and that 2-year inspections would lead to more violations.

Ms. Harvey asked the committee to explore different ways in which facilities might meet qualifications for interpretation. She would like to see more outcomes-oriented inspections.

Ms. Martin noted that the current system is paper based and is not practical for entities with multiple centers. Facilities that had digitized documents could present documentation at a

moment's notice. The committee concurred that electronic versions of documents verifying personnel qualifications should be acceptable. The committee agreed that attestations were unacceptable substitutes for actual documentation of credentials.

Many committee members suggested that some sort of centralized database for credentialing documents would be helpful to inspectors as well as facilities. Members discussed possible complications with trying to create such a system, including who would have access, who would input new information, and who would verify the accuracy of the data entered.

Dr. Finder noted that inspectors can accept scanned documents, but the guidance does not make that clear. The same practice group can have one set of documentation and use it for each inspection. Because all documentation must be current as of the date of inspection, and inspectors may not have Internet access when at a facility, it raises certain logistical problems in checking credentials via a national database.

Committee members agreed that the current continuing education requirement of 15 hours every 3 years is appropriate. Many members, however, also felt that assessment of interpretive skills could be useful and suggested that the Mammography Interpretive Skills Assessment should count toward the continuing education requirement. It might be more effective for inspectors to look at mammograms taken by each technologist than to look at records. Many committee members noted that outcome audits for radiologists could serve as a facility report card.

Dr. Finder noted that implementation of the requirement of 6 hours of modality-specific continuing education every 3 years has been pushed back to 2006. As in previous meetings, the committee agreed that this requirement was overly burdensome and could be deleted without a

decrease in mammographic quality. Committee members agreed that the initial 8-hour training requirement is still appropriate.

Committee members agreed that facility personnel should be responsible for maintaining their own continuing education records, but documentation of credentials is the facility's responsibility. Members noted that as we move into an age where images can be transmitted and interpreted anywhere, nationwide credentialing could become necessary. Because facilities vary in organization, some sort of template that shows how inspectors want records organized could be helpful.

Pam Wilcox, Assistant Executive Director, American College of Radiology (ACR), noted that ACR and the Radiological Society of North America are creating a database that enables members to keep track of their continuing education credits. Electronic verification of courses should be available.

Dr. Reichert suggested that the current guidelines are fairly indistinct as to what outcomes must be measured. A single outcome data sheet that everyone used—including information such as the number of mammograms read by each radiologist and the number of biopsy-proven cancers per thousand—would facilitate outcomes-based analysis. If a facility had data showing that it was diagnosing at least 4 breast cancers per 1000 mammograms, and proven biopsies are 25 percent, then perhaps the following year the facility could be exempt from showing CME forms; the regulatory burden could be reduced if statistics are appropriately high.

Equipment and Quality Control—Melissa Martin, Discussion Leader

Ms. Martin observed that the committee needs to make recommendations concerning facilities that have only FFDM units. The current requirements still include some tests that

require the use of film, but some FFDM facilities do not have film processors. These tests should not be required for digital units.

Ms. Mount stated that one test that has become redundant is the film-screen contact test. Her facility has yet to identify a bad cassette in its semi-annual testing. The committee concurred that testing once per year would be adequate.

The committee discussed whether the test for uniformity of screen speed could be done by the radiologic technologist (RT) instead of the physicist; the physicist could then review the results. The members concurred that the RT could conduct the test as long as the results were reviewed by the physicist. Committee members discussed ways to appropriately use older cassettes.

In response to a question from a committee member, **Walid G. Mourad, PhD, Inspection Support Branch, DMQRP,** noted that inspectors do not do physical tests such as collimation and dose on FFDM units. FDA asks inspectors to make sure the facility did what was required. Facilities must do the tests that are recommended by the modality manufacturer. He also pointed out that uniformity of screen speed is an annual test; film-screen contact is a semiannual test.

Kish Chakrabarti, PhD, DMQRP, noted that during mammography equipment evaluations and annual surveys, some tests require film processing. It was his belief that facilities should not have the additional burden of having to have a film processor; all manufacturers are looking to develop alternative testing methods that do not require the use of a film processor.

The committee discussed whether the physicist must be onsite before any patient films are processed (as in the current regulations), or whether the same quality could be obtained by having physicist oversight rather than physical presence. The panel concurred that the physicist

should review and approve quality assurance processes for the facility, but the physicist must exercise thorough oversight and communicate clearly whether the facility could start working with patients. It should not be the responsibility of the technologist to decide that everything is satisfactory. In these situations, the physicist should retain the responsibility for ensuring that films are adequate.

Committee members felt that a phantom image test density of 1.2 (the minimum allowed by the regulations) is too low. The committee agreed that as the film density is increased, the regulations should also increase allowable contrast fluctuation to accommodate high-contrast films. The committee suggested that the test density should use 1.6 as the aim and 1.4 as the minimum. They also recommended that phantom image quality should be set higher (increased number of objects imaged) as well.

Ms. Harvey asked whether any tests could be eliminated. Committee members observed that even though no violations were noted for dose and the test may be redundant, dose is of concern to the public. The Conference of Radiation Control Program Directors, which represents state radiation control programs, has a list of essential items for mammography inspections; the first three on the list all relate to dose. Mr. Camburn, stated that inspectors should continue to check these items during the annual MQSA inspection. Dr. Karellas stated that inspectors should be free to conduct tests if they see the need for them. Routinely measuring dose is not a good use of time. **Priscilla (Penny) Butler, Director, Breast Imaging Accreditation program, ACR,** stated that data show that testing kVp annually is not necessary—it is not something that fails.

Medical Records and Audit—Maryanne Harvey, MS, Discussion Leader

Ms. Harvey noted that the committee had touched on the topic earlier. She reiterated that a standardized data collection form would be helpful to facilities. Audits are intended to help facilities understand their own processes. Committee members discussed the difficulties with collecting data; for example, small centers have a hard time with data collection. It is important to have a person dedicated to data collection and entry.

Judy M. Destouet, MD, Chief of Mammography, Advanced Radiology, PA, Baltimore, MD, stated that her facility has a group of people who do nothing but collect medical audit data. It is expensive and time consuming, but useful. It allows them to assess the practice and determine who is doing a good job. The committee should recognize that this is an unreimbursed mandate placed on the facilities. Dr. Finder noted that the data are for the use of the facility; audits are intended to help facilities do self-analysis. The Agency was not trying to set a standard.

Dr. Reicher reiterated that FDA should encourage standardized medical audit data collection, which should separate diagnostic and screening data. With regard to reducing regulatory burden, Dr. Reicher stated that it is unclear whether digital facilities are allowed to provide clinical images on a CD-ROM. Dr. Finder noted that the policy guidance help system clarifies this issue. FFDM facilities must be able to produce hard copy images. Accreditation bodies need hard copy, as do most referring physicians. Electronically transmitting data between facilities is acceptable in those cases where the receiving facility agrees to accept electronic images.

Dr. Reichert suggested that CD-ROM drives are more available than clean viewboxes are and asked under what circumstances the requirement to have a printer would change. He also asked whether FDA could consider changing the record requirement so that the facility could

keep the previous two mammograms, or some other number not based on time. Dr. Finder replied that changing the record retention requirement would require a change in the law. Committee members noted that previous mammograms are helpful both for analyzing areas that have subtle changes and for increasing accuracy. The committee agreed that the current record-keeping requirements are acceptable.

Other Issues—Maryanne Harvey, MS, Discussion Leader

Ms. Harvey raised the issue of the future of stereotactic processes and noted that the committee has no regulatory authority over ultrasound. In response to a committee member's question, Dr. Finder said that facilities had been surveyed twice over the past several years as to where they perceive the greatest regulatory burdens are. **Nancy Wynne, Chief, Outreach and Compliance Branch, DMQRP,** said that no one issue surfaced from those surveys. Dr. Finder noted that many of the issues raised in the meeting are similar to those the Agency has received from individual facilities. Ms. Martin suggested that for facilities with multiple machines, if inspection of two machines exactly correlates with the physicist's test, it should not be necessary to inspect all machines in a facility. This approach would reduce the down time associated with inspections and testing, which is a big issue.

Several committee members again noted that even though it might not be necessary, dose testing is important to the public and should not be eliminated. One member noted that dose could be calculated indirectly so that actual testing could perhaps be eliminated.

Tammy Correll, Mammography Technologist, State of Missouri, raised several issues:

?? Inspection does not cover viewing conditions, which are often poor. ACR and other bodies state that technologists should have the same viewing conditions as radiologists.

?? The inspector's phantom is different from the facility phantom; it would be good for inspectors to use facility phantoms. A lower limit should be set for phantom density.

?? The way deficiencies are assessed implies that quality control is not as important as other issues.

?? The State of Missouri conducted a review of films in conjunction with inspection. Facilities that did well with MQSA and ACR have had some of poorest films in the State. The results were most closely correlated with the number of exams the facility does.

Richard Lippert, President, mammologix a division of i/oTrak, reminded the committee that the goal of MQSA is to measure performance. He referred to the Institute of Medicine recommendations and said that currently, no performance standard exists.

Jerry Thomas stated that FFDM increases the quality control burden because additional tests are required. It was his opinion that manufacturer quality control programs are poor to nonexistent. Units from different vendors have different quality control systems. Penny Butler stated that ACR is currently working on a quality control manual for all FFDM units to address the issues that Mr. Lippert and Dr. Thomas raised.

The committee agreed that the guidance should include viewbox requirements.

MEDICAL DEVICE REGULATION OF PACS DEVICES

Robert Phillips, PhD, Chief, Radiological Devices Branch, ODE, reviewed device classification and market clearance processes, including 510(k) and PMA procedures. Picture archiving and communication system (PACS) devices were classified about 15 years ago. They

are preamendment devices that are divided into five components: workstation (including CRTs and other soft-copy devices), communications devices, data storage devices, hard-copy output devices, and digitizers. Communication and storage devices were placed in Class I and are exempt from 510k submission. Hard-copy, digitizer, and workstation components were placed in Class II and require a 510k submission.

Dr. Phillips discussed the use of compression technology in PACS devices. Compression ratios for lossy compression have improved from 4:1 about 15 years ago to 40:1 with current JPEG 2000 technology. All images derived following lossy compression must carry a warning label. Lossy compression has not been cleared for mammography use. One problem with transmission of electronic data is that phone company compression utilities may be automatically applied to minimize bandwidth, affecting the image. Digitizers, which convert conventional images into digital images, are not cleared for mammography use, except for CAD devices.

Dr. Finder asked the committee to discuss acceptable uses of digitized film-screen mammography. What methods can FDA use to ensure quality, safety, and effectiveness? He also asked the committee to discuss the use of digital data compression in image storage and transmission. Committee members concurred that, in the absence of a clinical trial to evaluate the impact of lossy compression on accuracy of reading, it is important to keep an original, nonlossy digital image. Dr. Karellas noted that his research is demonstrating equivalence for compressed and noncompressed readings.

Dr. Finder then asked whether requirements or standards for treating compressed data as original should be developed. Dr. Phillips noted that the question may become moot as time goes on due to technological innovations.

Julian Marshall, R2 Technology, Inc., raised the issue of the difficulty of looking at CRTs and viewboxes simultaneously. He also noted that not all film digitizers are the same; for example, some digitizers exhibit fixed-pattern noise. If the compression algorithm adds shapes, it affects the CAD algorithm. The problem is that not all compression algorithms are standardized.

Dr. Reichert noted that one can digitize an image and reproduce it faithfully enough to find a single calcification. He also suggested that monitor standards must be defined on the basis of resolution. The regulations should require that an image be displayed at full resolution at some point in the reading process, and software should indicate whether an image is being displayed at full resolution. One can have mathematically lossy data that is visually lossless. Mr. Marshall cautioned that if compression artifacts are introduced to images, CAD algorithms designed to look at temporal change might not work.

Dr. Finder asked whether it was acceptable for facilities to digitize a film-screen image for specific purposes (e.g., comparison, referring physicians) as long as they kept the original. The committee concurred that doing so would be acceptable. Committee members brought up the point that readers do not want to have to look at bright viewboxes and dim monitors at the same time and therefore there would be benefits to allowing old comparison film-screen images to be digitized and displayed on monitors. It is believed that a substantial number of cancers could be missed because of the inability of the eye to adjust to the two types of viewing devices simultaneously. Jerry Thomas noted that film digitizers have differing D_{max} (the optical density above which the digitizer will not accurately reproduce the density of the original image). Most digitizers also create noise in the reproduced image. While it appears that film digitization makes sense within certain standards, dynamic range and noise are concerns.

Dr. Barr provided statistics on the current number of mammography facilities. She noted that the committee will be asked to discuss stereotactic devices in the future. Dr. Finder provided background on why the regulations do not cover viewboxes.

MQSA GUIDANCE

Dr. Finder asked the committee to discuss several questions.

1. For facilities that scan paper records and personnel documents for use in inspections, what should be the hard-copy requirements? Does the facility have to maintain some records in hard copy? What about records generated by the facility itself? Do facility quality control tests have to be maintained in the original format?

The committee agreed that the facility could use electronic versions of the records but should maintain backup versions (either electronic or hard copy).

2. What should facilities do when a patient does not want the lay summary of her mammogram? Under the regulations, patients must be sent lay summaries of mammograms.

Committee members noted that the situation was rare and recommended placing the lay report with the medical report in the patient's chart. Patients should sign a release stating that they did not want a copy of the lay report.

3. Should the Agency include small field digital mammography as some segment of FFDM in terms of personnel qualifications? Should it request that people who use these units get some sort of training in FFDM?

Committee members agreed that the units are very different from FFDM units. Users need at least the manufacturer's training and must follow the manufacturer's recommended quality control program. The committee concurred that people used to film-screen devices should not use the devices without training. Eight hours of FFDM training would be acceptable.

OTHER COMMITTEE BUSINESS

The committee reviewed and approved the summary minutes from its April 2003 meeting. Dr. Finder noted that a meeting would be scheduled for fall 2004 to discuss reauthorization issues.

ADJOURNMENT

Ms. Harvey thanked the participants and adjourned the meeting at 4:24 p.m.

I certify that I attended this session of the National Mammography Quality Assurance Advisory Committee on April 19, 2004, and that these minutes accurately reflect what transpired.

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Charles Finder, MD
Executive Secretary

I approve the minutes of the April 19, 2004, meeting as recorded in this summary.

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Maryanne Harvey, MS
Chairperson

Summary prepared by
Caroline G. Polk
Polk Editorial Services
1112 Lamont St., NW
Washington, DC 20010
(202) 265-8271
cpolk@earthlink.net